The following corrections or additions to the January 2005 list were published in the Federal Register in June 2005.

New Approvals

NADA Number: 141-245

Trade Name:	Tributame™ Euthanasia Solution
Ingredients:	Embutramide, chloroquine phosphate U.S.P, and lidocaine U.S.P
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	May 20, 2005
Status:	Prescription only
Route:	Intravenous
Species:	Dogs
Drug Form:	Liquid (solution)
Concentration:	135 milligrams embutramide, 45 milligrams chloroquine phosphate, and 1.9 milligrams lidocaine per milliliter
Indications:	For euthanasia in dogs only.
Patent number:	5,290,775 Expiration date: March 1, 2011 5,281,611 January 25, 2011
Exclusivity:	3 years

21CFR 522.810

NADA Number: 141-220

Trade Name:	Cydectin® Injectable Solution for Beef and Nonlactating Dairy Cattle
Ingredients:	Moxidectin
Sponsor:	Fort Dodge Animal Health Division of Wyeth
Approval Date:	May 20, 2005
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle (beef and nonlactating dairy)
Drug Form:	Liquid (solution)
Concentration:	10 milligrams per milliliter
Indications:	For the treatment and control of the following internal and external parasites of cattle: **Gastrointestinal Roundworms**: *Ostertagia ostertagi* (adults and inhibited fourth-stage larvae), *Haemonchus placei* (adults), *Trichostrongylus axei* (adults), *Trichostrongylus colubriformis* (fourth-stage larvae), *Cooperia oncophora* (adults), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia surnabada* (adults and fourth-stage larvae), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris spp*. (adults); **Lungworms**: *Dictyocaulus viviparus* (adults and fourth-stage larvae); **Cattle Grubs**: *Hypoderma bovis*, *Hypoderma lineatum*; **Mites**: *Psoroptes ovis (Psoroptes communis var. bovis)*; **Lice**: *Linognathus vituli*, *Solenopotes capillatus* Persistent Activity: Cydectin® Injectable has been proven to effectively protect cattle from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 42 days after treatment, *Haemonchus placei* for 35 days after treatment, and *Ostertagia ostertagi* and *Trichostrongylus axei* for 14 days after treatment.
Patent number:	4,916,154 Expiration date: April 10, 2007 5,965,603 July 8, 2018
Tolerance:	*21 CFR 556.426* Moxidectin: The tolerance for parent moxidectin (the marker residue) is 900 parts per billion in fat, 200 parts per billion in liver, 50 parts per billion in muscle, and 40 parts per billion in milk.
Withdrawal:	21 days
Exclusivity:	3 years

21CFR 522.1450 and 556.426

Actions Taken by FDA Center for Veterinary Medicine

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-177

Approval Date: June 1, 2005

This application provides for a new container size of 7.5 gram dropper bottle.

21CFR 524.1044h

Change of Sponsor's Name

From: Steris Laboratories, Inc.
To: Watson Laboratories, Inc.
Drug Labeler Code: 000402

From: Rhodia Limited
To: Rhodia UK Limited
Drug Labeler Code: 059258

Addition of Patent Number(s)

NADA Number(s): 141-216

Patent Number:	**Expiration Date:**
6,893,652	July 24, 2022

Change of Trade Name

ANADA 200-364 From: SpecMed™ Scour-Check™
To: Spectrogard Scour-Chek™.

Change of Sponsor

NADA Number(s): 011-779, 013-214, 013-663, 040-205, 042-116, 042-660, 043-387, 046-700, 049-729, 097-258, 099-767, 113-748, 132-574, 135-941, 136-116, 140-869

From: Purina Mills, Inc.
To: Virbac, AH, Inc.

Drug labeler code: 051311

Notice(s)

The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including renewal of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for distribution and use of Veterinary Feed Directive (VFD) drugs and animal feeds containing VFD drugs.

Submit written or electronic comments on the collection of information by August 9, 2005. Submit electronic comments on the collection of information to http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

For further information contact: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B-41, Rockville, MD 20857, 301-827-1472.

The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled “General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (GFI 3)." This version of the guidance replaces the version that was made available in July 1994. This has been revised to remove outdated information on toxicological testing and to provide references to other available guidance on the topic. In addition, the document has been revised to address minor formatting issues. Submit written or electronic comments on agency guidances at any time.

Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

For further information contact: Mark M. Robinson, Center for Veterinary Medicine (HFV-150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5282, e-mail: mrobinson@cvm.fda.gov.

Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern (OMB Control Number 0910-0522)

In the Federal Register of January 6, 2005 (70 FR 1253), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received on this information collection. This guidance discusses an approach for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern. In particular, the guidance describes methodology that sponsors of antimicrobial new animal drug applications for food-producing animals may use to complete a qualitative antimicrobial resistance risk assessment. This risk assessment should be submitted to FDA for the purposes of evaluating the safety of the new animal drug to human health. The guidance document outlines a process for integrating relevant information into an overall estimate of risk and discusses possible risk management strategies. The Food and Drug Administration (FDA) is announcing that the proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. Fax written comments on the collection of information by August 1, 2005.

OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974. For further information contact: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B-41, Rockville, MD 20857, 301-827-1472.